UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION NO. II, This Document Relates To: All Cases	MDL No. 1:22-md-03029-PBS

PLAINTIFFS' SUBMISSION ON OUTSTANDING CASE MANAGEMENT ISSUES

After an extensive conferral process on three case management orders, narrow issues remain in dispute for which the parties need the Court's guidance. The orders at issue are (1) a Proposed Scheduling Order[1] [ECF No. 48-1]; (2) Proposed Order Governing the Production of Hard Copy Documents and Electronically Stored Information ("ESI") [ECF No. 48-2]; and (3) Proposed Confidentiality and Protective Order [ECF No. 48-3].

Plaintiffs' positions on the remaining issues are set forth below. In support of their positions, Plaintiffs show the Court the following:

I. THIS COURT SHOULD ADOPT PLAINTIFFS' PROPOSED SCHEDULING ORDER.

As of September 30, 2022, three issues remained in dispute on the scheduling order. *See* ECF No 48-1. In the spirit of compromise, Plaintiffs agreed to everything but the deadline for completion of general corporate discovery, which is the one issue that now remains in dispute. *Id.* at 2 (Sec. II). Specifically, Defendants propose September 30, 2023 and Plaintiffs propose April 8, 2024 as the deadline for completion of corporate discovery for the initial bellwether cases. Defendants did not share Plaintiffs' compromising spirit but rather, in exchange for adopting

[1] As discussed further below, Defendants have made one date on the scheduling order contingent on coordination between the MDL and the state court—a much larger and significant issue than a single date on a scheduling order.

Plaintiffs' reasonable date, Defendants proposed a draconian coordination procedure with the state court proceeding that would prejudice all plaintiffs in this MDL. When Plaintiffs declined to accept Defendants' "offer," Defendants indicated that today's submission would include the concept of coordination. But that is not what is at issue in this submission. To be sure, the only question the Court needs to answer for the scheduling order CMO is whether Plaintiffs get less than a year to work-up a major MDL case for trial or, the more reasonable time frame of 18 months that Plaintiffs propose. This Court should allow the Plaintiffs 18 months to conduct discovery.

A. The Court Should Adopt Plaintiffs' April 2024 Date in Section II.

This matter was consolidated in June of 2022 and Defendants have yet to produce a single document. Plaintiffs anticipate that Defendants will eventually produce hundreds of thousands of documents amounting to millions of pages. Document review of this magnitude takes a significant amount of time.

Further, there are over twenty products at issue in this MDL, which were cleared at different times with different employees responsible for the design, manufacture, marketing, and regulatory submissions. The sheer number of likely witnesses alone justifies Plaintiffs' modest request of 18 months to conduct discovery. Of course, Plaintiffs will not know who the significant players are for each product until they have had an opportunity to begin reviewing the documents (documents that, again, have not even been produced).

Defendants' proposal gives Plaintiffs less than a year to review millions of pages of documents, notice dozens of corporate depositions, and then get those depositions scheduled. This is simply not workable and will prejudice the plaintiffs in this MDL. This is a major MDL with thousands of cases anticipated. The stakes are simply too high to force Plaintiffs to finish discovery for the first trials in less than a year. Therefore, due to the high likelihood of prejudice

to the Plaintiffs if not given enough time, this Court should adopt Plaintiffs' proposal of April 2024.

B. Forced Coordination with the State Court Proceeding Should Not Be Ordered.

At the last minute, Defendants made this submission about coordination with the Massachusetts Superior Court case in Middlesex County (the "MA State Court" Proceeding). Plaintiffs argue that there should not be any forced coordination with the MA State Court Plaintiffs as they have a different focus that is already split between the multifilament products and the non-multifilament products,[2] each of which already requires separate time for questioning a corporate witness by different attorneys. Put simply, MA State Court is on a different timeline, and has a different approach to the litigation of these cases.

The Plaintiffs' leadership in this MDL sees these cases differently than the MA State Court Plaintiffs' leadership, and intends to prosecute the bellwether cases, and this MDL, differently than Plaintiffs' leadership in the MA State Court. While coordination between similar litigations occurring in different jurisdictions could be useful, that is not the case here given the different legal theories and distinct approaches to these cases between the Plaintiffs' leadership in the MA State Court and this MDL. The Court in the Bard Hernia Mesh MDL in Ohio recently agreed stating that "[t]he Plaintiffs' Steering Committee ('PSC') has consistently represented that their approach to this litigation is significantly different than that of the Rhode Island Plaintiffs in the state court MDL. The Court believes that the PSC is entitled to conduct discovery consistent with its own legal theories of the case and its own view of the fact." See *In re: Davol, Inc./C.R. Bard,*

[2] A separate leadership structure was created in the MA State Court to advance the interests of the non-multifilament plaintiffs in respect to general liability discovery, expert development, and motion practice, as the Multifilament Plaintiffs' Leadership in MA State Court made it clear that they would not work up those cases as they believe there is a conflict of interest in representing both multifilament cases and non-multifilament cases. Multifilament Pls.' Br. in Supp. Of Multifilament Pls.' Mot. For Docket Control Order at pp. 2, 8-10; Non-Multifilament Pls.' Reply in Supp. Of Non-Multifilament Pls.' Mot. for Docket Control Order at pp. 2-3.

Inc., Polypropylene Hernia Mesh Products Liability Litigation, MDL 2846, Doc. No. 156, Order at pp. 2. Plaintiffs respectfully ask this Court to take the same approach the Court did in MDL 2846.

Additionally, due to the status of the Plaintiffs' leadership in the MA State Court and the way they are already proceeding with these depositions on two different tracks separating the products out, there is no way that Plaintiffs' leadership in this MDL could also take the witness's deposition on the same date. As such, the most that would be accomplished through these cross-noticed depositions is that these witnesses would be deposed on two consecutive days, as opposed to potentially two days that are non-consecutive. Given the Plaintiffs' leadership's distinct approach to these cases in this MDL as well as the structure and position of the MA State Court's leadership, there would be little efficiency gained by allowing Defendants to cross-notice the depositions of their corporate witnesses in the MA State Court Proceeding.

If this Court is inclined to agree or even entertain the idea of allowing Defendants to cross-notice the depositions of their corporate witnesses in the MA State Court, Plaintiffs request that the Court allow the parties to provide briefing on these issues as Plaintiffs' leadership will need time to figure out the procedure, timing, and other issues involved in coordinating these depositions in these two separate litigations that will include at least three separate attorneys questioning each witness.

For purposes of the CMOs at issue in this submission, the Court does not need to decide coordination issues now. Indeed, independent of any coordination between the MDL and the state court, the MDL Plaintiffs need 18 months to conduct discovery necessary to prosecute these cases. Anything short would prejudice Plaintiffs significantly.

II. THIS COURT SHOULD ADOPT PLAINTIFFS' POSITIONS ON THE DISAGREED PORTIONS OF THE PROPOSED ELECTRONICALLY STORED INFORMATION ("ESI") CASE MANAGEMENT ORDER.

The parties have three discrete areas of disagreement contained within the draft proposed Case Management Order ("CMO) regarding ESI. Because the Plaintiffs' position more closely tracks the manner in which the Federal Rules of Civil Procedure require ESI production to be handled, this Court should adopt Plaintiffs' positions on each of the three areas.

A. The Federal Rules of Civil Procedure require producing parties to continuously supplement prior productions.

It is important to recognize that while, the MDL Plaintiffs have worked very hard to achieve the Defendants' of maximizing the efficiencies which can be achieved from their prior discovery in the Massachusetts state court action, the MDL Plaintiffs cannot agree to curtail the discovery they are entitled to under the Federal Rules of Civil Procedure. Leadership in the MDL was not involved and took no part in the master discovery in the Massachusetts state court action and the Federal Rules do not contemplate the Federal litigants as having to agree to accepting as "complete" what state court discovery has been done for certain custodians. As this Court has heard previously, the Massachusetts state court plaintiffs have chosen a different focus of discovery than will the MDL Plaintiffs and, while there is efficiency to be had with the production of the prior state court discovery in this MDL, the production of that prior state court discovery does not obviate the obligations the producing party has under the Federal Rules.

The chief area of disagreement with regard to paragraph I(I) of the proposed ESI CMO is about the need to supplement and validate the state court production if Defendants desire to produce it in this MDL. Federal Rule of Civil Procedure 26(e) would require these Defendants to supplement that prior discovery if it previously had been produced in this MDL. Defendants now

wish to adopt a prior state court production but, having chosen to do that, Defendants cannot claim that their Rule 26(e) obligation to supplement and validate the prior production no longer pertains.

The MDL Plaintiffs certainly agree that Defendants' production of the prior production will streamline the initial production in this litigation but cannot agree to strike through Defendant's duty to supplement that discovery. Accordingly, paragraph I(I) of the ESI CMO should contain the following provision proposed by Plaintiffs: "Further, the producing party will update the custodial files and/or databases so that the prior production is updated and current to the present time." The ESI CMO also not include the following provision proposed by Defendants: "a party is not obligated to re-validate that production set and is not obligated to re-collect the Documents that formed the basis for that production."

B. Defendants should produce all responsive email threads as they are kept in the ordinary course of business.

In paragraph III(H) of the proposed ESI CMO, Defendants seek to curtail their discovery obligations relating to the production of emails in a manner which would produce only the latest email in a "thread email" so long as it contained all the attachments. In this manner, Defendants would be voiding the language of Federal Rule of Civil Procedure 34(b)(2)(E)(i) which requires: "a party must produce documents as they are kept in the usual course of business or must organize and label them to correspond to the categories in the request."

Defendants do not contest that they have the "lesser included emails" in their possession but do not want to produce them except as part of a single ESI document email thread. The challenge with that manner of production is that prior emails within a thread each contain their own meta-data which can be lost when threaded.

See, e.g., In re Actos Anti-Trust Litig., 340 F.R.D. 549, 552 (S.D.N.Y. March 30, 2022). In the *Actos Anti-Trust* case, the Magistrate Judge ruled that, because the parties had not stipulated

to receiving only the most current most-inclusive email in a thread, the producing party was short-changing the receiving party of some critical ESI:

> Takeda's exclusion of lesser included emails from production has resulted in the exclusion of the metadata associated with earlier emails in a chain (which may be weeks or even months prior to the last email in a chain)…This exclusion materially has reduced Plaintiffs' ability to search for all correspondence within a date range. In addition, in certain email chains, only the sender of particular emails earlier in a chain are reflected, and not the recipients of such emails…Finally, Takeda's email threading has removed Plaintiffs' ability to see if anyone was blind-copied on lesser included emails, even though this information was among the metadata the parties agreed in the Discovery Protocol to produce.

Id.

Because Plaintiffs have not agreed, and do not agree, to limit email productions as proposed by Defendants, Defendants would be at an unfair advantage in terms of the electronically stored information because Defendants would have access to meta-data and information that, through the email thread approach would be foreclosed to Plaintiffs. In the several conversations which Plaintiffs' counsel had with Defendants' counsel about this provision, Defendants never identified the "undue burden" which could be obviated through the email-thread approach.

As such, this Court should rule in the ESI CMO that Defendants stick to the Rule 34 requirement that documents, including ESI, be produced as they are kept in the ordinary course of business and therefore not include within the CMO the current paragraph III(H) proposed by Defendants.

C. Defendants should produce an appropriate privilege log within thirty days of the withheld production.

In paragraph V(A) of the proposed ESI CMO, the disputed language concerns when a producing party is required to produce a privilege log. Plaintiffs propose "monthly" while Defendants propose the term "on a continuing basis". The problem with the term "on a continuing basis" with regard to the privilege log obligation is that it leaves too much to be defined and does

not set a specific timeline for when the producing party is required to produce the privilege log. Fortunately for the parties and the Court, there is a readily ascertainable answer as to when a party is required to produce a privilege log detailing the document withheld from production.

Federal Rule of Civil Procedure 26(b)(5) requires parties to produce the information (contained within what is now colloquially called a "privilege log") when the document is withheld and requires the party to "describe the nature of the documents, communications, or tangible things not produced or disclosed—and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim". Failure to produce timely the privilege log can be viewed by this Court as a waiver of the privilege. Fed.R.Civ.P. 26(b)(5) advisory committee's notes (1993 amendments). The time to assert the privilege and provide the required privilege log information through Rule 26(b)(5) is typically seen as falling at the same time as the obligation to respond to request for production of documents, i.e., 30 days. *Burlington Northern & Santa Fe Ry. Co. v. U.S. District Court for District of Montana*, 408 F.3d 1142, 1149 (9th Cir. 2005) (citing Federal Rule of Civil Procedure 34).

Recognizing that there will be a rolling production, in the proposed ESI CMO, Plaintiffs have proposed privileged logs be produced on a monthly basis so that asserted privileges and the required privilege log is produced at the time of the production from which the allegedly privileged document was withheld from production. Defendants' proposal simply that it be on a "continuing basis" does not adequately define the timeframe during which the Rule 26(b)(5) privilege log information must be provided. This Court should clearly define the producing party's obligation to assert the privilege and provide the information required by Rule 26(b)(5). Adopting the Plaintiffs' proposed language about the production of privilege logs on a monthly basis serves that end.

III. THIS COURT SHOULD ADOPT PLAINTIFFS' POSITION ON THE DISAGREED PORTION OF THE PROPOSED CONFIDENTIALITY AND PROTECTIVE ORDER.

The area that remains in dispute on the proposed protective order can be boiled down to the following question: Should Plaintiffs be forbidden from using a document with certain witnesses simply because Defendants chose to mark it "HIGHLY CONFIDENTIAL"? The answer must be "No." Otherwise, Plaintiffs will be irreparably harmed.

If Defendants' position prevails, it will have the obvious and tangential impact of directly interfering with Plaintiffs' ability to show corporate documents relating to the safety and risks of hernia mesh devices to the very witnesses that Defendants likely will claim were already aware of the risks at issue.

Where the disputed language is most likely to have a critical impact on plaintiffs' ability to prosecute these cases is during the deposition of an implanting and/or explanting physician for a potential bellwether case—specifically, the surgeon who recommended and implanted the hernia mesh in a given plaintiff or, the surgeon who removed it. Defendants will undoubtedly assert a Learned Intermediary defense in these actions, arguing that implanting surgeons were adequately warned of the safety and risks inherent in hernia mesh devices or alternatively, there was no need to warn because the medical community was already aware of such risks. This Learned Intermediary defense is typically a cornerstone of manufacturers' defense in pharmaceutical and medical device failure to warn cases. *See, e.g., Payne v. Novartis Pharmaceutical Corp.*, 767 F.3d 526, 530–33 (6th Cir. 2014).

Because of the Learned Intermediary defense, during depositions of implanting physicians, it is necessary for Plaintiffs to explore what risks the surgeon knew prior to implanting the device; what risks were disclosed to plaintiffs; and whether the addition of

additional safety information would have impacted the physician's decision to recommend the device and/or affected physician's risk/benefit discussion with the patient. This may require showing such a witness internal documents where company employees discussed or analyzed the safety of the product at a deposition, to determine whether knowledge of such information would have impacted the doctor's decision and/or discussion with the patient/plaintiff. These implanting doctors are often asked the follow-up question by plaintiffs' counsel "if you were aware of this information would you have imparted that to your patient." Without the ability to confront a physician with such a document (because it has been marked "Highly Confidential") would severely prejudice Plaintiffs' right to challenge this critical defense.

A. Standard of Review

Pursuant to Rule 26 of the Federal Rules of Civil Procedure, "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" FED. R. CIV. P. 26(c). '"The burden of establishing good cause for a protective order rests with the movant."' *Snelling v. ATC Healthcare Servs.*, No. 2:11-CV-00983, 2013 U.S. Dist. LEXIS 49105, at *5–6 (S.D. Ohio Apr. 4, 2013) (Sargus, J.) (quoting *Nix v. Sword,* 11 F. App'x 498. 500 (6th Cir. 2001)). "To show good cause, the [moving party] must articulate specific facts showing clearly defined and serious injury resulting from the discovery sought and cannot rely on mere conclusory statements." *United States ex rel. Daugherty v. Bostwick Labs.*, No. 1:08-cv-354, 2013 U.S. Dist. LEXIS 89683, at *39 (S.D. Ohio June 24, 2013) (internal quotations omitted).

The entry of a protective order rests with the sound discretion of the Court. *Procter & Gamble Co. v. Bankers Trust Co*., 78 F.3d 219, 227 (6th Cir. 1996). Nevertheless, the Court's discretion to issue protective orders is "limited by the careful dictates of [Rule] 26 and 'is

circumscribed by a long-established legal tradition' which values public access to court proceedings." *Id*. (citing *Brown & Williamson Tobacco Corp. v. Fed. Trad Comm'n*., 710 F.2d 1165, 1177 (6th Cir. 1983)).

B. Plaintiffs will Suffer Significant Prejudice if an Implanting Physician Cannot Be Shown Confidential Information.

The Court should weigh the minimal risk of disclosure against the potential prejudice to Plaintiffs if they are unable to show a witness relevant documents during a deposition. As described below, this prejudice will be significant.

1. Plaintiffs' Failure to Warn Claims and Defendants' Learned Intermediary Defense

As the Court is aware, in this litigation, Plaintiffs are asserting, in part, that Defendants failed to adequately warn doctors of known risks inherent to hernia mesh implants. By contrast, Defendants assert a learned intermediary defense, contending that implanting physicians knew of all the risks relating to hernia mesh implantation. It is critical, therefore, that Plaintiffs be able to determine:

- What risks the implanting surgeon was aware of at the time the hernia mesh was implanted in plaintiff;
- what risks were discussed with the plaintiff when making the decision to implant hernia mesh; and
- where additional safety information was known to Defendants but not disclosed to doctors, whether knowledge of these risks would have impacted the prescribing decision and/or the doctor's discussion of safety risks with the plaintiff.

Such a determination will likely require Plaintiffs to show an implanting surgeon safety information that was known internally to Defendants' employees. For example, if Covidien's scientists internally acknowledge in an email the risk of chronic pain for patients implanted with hernia mesh but this injury is not included in the product labeling, then whether such information

would have impacted the implanting surgeon's decision to use Covidien hernia mesh and/or that doctor's discussion about the risks and benefits of such treatment with the plaintiff is highly relevant to Plaintiffs' claims and Defendants' defenses. The inability to show such a document to a doctor would have a highly prejudicial impact on plaintiff's case.

Under the Plaintiffs' proposed Protective Order language, Plaintiffs would be able to show such an email to an implanting surgeon at a deposition. However, under Defendants' proposed Protective Order, Plaintiffs would be unable to show a witness such information. Such an outcome would greatly inhibit both parties' ability to test the claims and defenses in this case. Additionally, it would impede both parties' ability to determine what the witnesses actually knew and the impact of additional information on their decision-making. The risk of such prejudice is too great and the consequences too significant to adopt Defendants' proposal. This is particularly true where the risk of improper disclosure is so minimal.

1. Use of Deposition Testimony at Trial

Additionally, implanting physicians—who are usually located in the claimant's state of residence—are typically not available to testify in person at trial. Therefore, it will be necessary to play their videotaped deposition or read the transcript into the record. Defendants' proposed Protective Order would create an unfair disadvantage to plaintiffs because they might be prohibited from using certain documents at deposition—a deposition that would ultimately be played at trial—merely because it is designated "HIGHLY CONFIDENTIAL" (even where the witness signs an Acknowledgement or verbally agrees on the record to keep such information confidential). By contrast, if an implanting surgeon were testifying live at trial, there would be no prohibition on showing them these documents. Such a disparity cannot be permitted. The evidence that a plaintiff is able to introduce at trial should not be dictated by Defendants'

designation of confidentiality, particularly where there is so little risk of disclosure and where the witness agrees to keep such information confidential. Accordingly, Defendants' proposed Protective Order should be rejected by this Court.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' respectfully request the Court adopt their proposals on the Case Management Orders at issue in this submission.

Dated: September 30, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of October 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

/s/ *Kelsey Stokes*
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